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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,217	07/15/2005	Takao Shimizu	SAE-0036	6601
23353 7590 05/16/2008 RADER FISHMAN & GRAUER PLLC LION BUILDING 1233 20TH STREET N.W., SUITE 501 WASHINGTON, DC 20036				
EXAMINER				
LI, RUXIANG				
ART UNIT		PAPER NUMBER		
1646				
MAIL DATE		DELIVERY MODE		
05/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/542,217

**Applicant(s)**

SHIMIZU ET AL.

**Examiner**

RUIXIANG LI

**Art Unit**

1646

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4, 6-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-8, and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. Applicants' amendment filed on 02/14/2008 has been entered in full. Claims 5 and 9 are canceled. Claims 4, 6, and 7 are amended. Claims 10-18 are added. Claims 4, 6-8 and 10-18 are pending. Claims 17 and 18, drawn to a method for screening an agonist or an antagonist to the LPA receptor, are under consideration. All other claims are withdrawn from consideration.

### ***Withdrawn Objections and/or Rejections***

2. All the rejections and objections set forth in the previous office action are withdrawn in view of the canceled and amended claims.

### ***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17 and 18 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 17 and 18 are drawn to a method of screening substances in test samples that enhances or inhibits LPA dependent LPA activity, comprising monitoring binding of the test samples to G protein-coupled protein p2y9, wherein the p2y9 protein comprises an amino acid sequence having a sequence identity of more than 95% to SEQ ID NO: 1. The claims are drawn to a genus of p2y9 protein variants. However, the claims do not require that the p2y9 proteins possess any particular any particular conserved structure or biological function.

The instant disclosure of the p2y9 protein of SEQ ID NO: 1 does not adequately support the scope of the recited genus, which encompasses a substantial variety of homologues or variants of the p2y9 proteins. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While disclosing the amino acid sequences of SEQ ID NO: 1 and its ligand, the instant disclosure fails

to provide sufficient description information, such as definitive structural of the recited genus of p2y9 protein variants. There is no description of the conserved regions that are critical to the function of the genus recited. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. While the prior art teaches the amino acid sequence of SEQ ID NO: 1 (see, e.g., Sathe et al., US Patent No. 6,010,877), it does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed p2y9 proteins or a mutant thereof.

Due to the breadth of the recited genus and lack of the definitive structural and functional features of the recited genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of p2y9 protein variants and thus the instantly claimed methods.

***Claim Rejections—35 U.S.C. § 112, 2<sup>nd</sup> paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 17 and 18 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i). claims 17 and 18 are indefinite because they recite “substances”. It is unclear what the metes and bounds of the term are. It is suggested that “substances” be amended to, such as “a candidate compound”.

(ii). Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The monitoring of binding of the test samples to a G protein-coupled protein p2y9 cannot identify a compound that enhances or inhibits the LPA activity. The omitted steps are: how to determine the enhancing or inhibitory effect of a test compound on LPA-dependent LPA activity.

(iii). Likewise, claim 18 recites "the substances are further screened for effects on carcinoma cell invasion". However, the claim does not set forth steps with respect to how to screen such an effect.

***Claim Rejections—35 USC §102 (b)***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 17 is rejected under 35 U.S.C. 102(b) as being by anticipated by Sathe et al. (US 6,010,877, Jan. 4, 2000).

Sathe et al. teach a ligand binding assay comprising monitoring binding of a test sample to a G protein coupled receptor (SEQ ID NO:2) that is 100% identical the p2y9 protein of SEQ ID NO: 1 of the present invention, meeting the limitations of claim 17.

***Conclusion***

9. No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/  
Primary Examiner, Art Unit 1646

May 12, 2008